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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/601,997 | 12/15/2000 | James G. Keck | 24743-2307US | 5984 |

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| EXAMINER | |
|---|---|
| EPPS FORD, JANET L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1633 | |

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/601,997 | KECK, JAMES G. | |
| | Examiner | Art Unit | |
| | Janet L. Epps-Ford | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8-14 and 58-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14 and 58-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8-08-2000* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-05-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 8-14, and 58-72 have been considered but are moot in view of the new ground(s) of rejection, in response to Applicant's amendment to the claims filed 8-03-05.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-14, and 58-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following rejected was necessitated by Applicant's amendment to the claims filed 8-03-05.

4. The instant claims are drawn to a high-throughput method of assigning a function associated with a product coded for by a sample nucleic acid sequence in a target nucleic acid molecule. The method comprises wherein the members of the oligonucleotide family comprise a plurality of nucleic acids each encoding a transcription product comprising a sequence that is complementary to a sequence contained in the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence. The method further states, "the coding sequences for each individual transcription product encodes an antisense nucleic acid that when expressed as RNA, binds to the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence."

5. The metes and bounds of the claimed method are vague and indefinite because the nature of the transcription product is vague and indefinite, the claim recites that the transcription product possess a sequence that is complementary to a sequence contained in the mRNA transcribed from the target nucleic acid molecule, the claim then further recites that the coding sequence for the transcription product encodes an antisense nucleic acid that binds to the mRNA transcribed from the target nucleic acid molecule. It is the examiner's understanding that the transcription product that comprises a sequence that is complementary to the mRNA transcribed from the target nucleic acid molecule, is already "antisense" to the mRNA transcribed from the target nucleic acid molecule by means of its complementary sequence. It is unclear if the claim encompass an additional antisense molecule (see lines 15-18) beyond that of the transcription product described in lines 11-14 of this claim.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 8-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent No. 6,355,415 B1) in view of Gudkov et al. (US Patent No. 5,753,432), for the reasons of record.

8. Applicant's arguments filed 8-03-05 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the instant

method differs from Wagner et al. in view of Gudkov et al. to the extent that the oligonucleotide family used in their claimed method is not designed based on a discrete selection of molecules that will effectively and/or selectively bind to and/or cleave the target mRNA. According to Applicants regardless of whether their transcription products are effective antisense or ribozyme molecule, are used to make up the oligonucleotide family library. Contrary to Applicant's assertions, the oligonucleotide family used in their claimed methods are required to comprise a plurality of nucleic acids each encoding a transcription product comprising a sequence that is complementary to a sequence contained in the mRNA transcribed from the target nucleic acid molecule that comprises the sample nucleic acid sequence. Therefore, the oligonucleotide family has to comprise sequences that produce antisense, i.e. "complementary" structures that bind to the mRNA transcribed from the sample nucleic acid. The claims do not state that the antisense oligonucleotide inhibit the expression of the mRNA from the sample nucleic acid, however, in order to identify a phenotype and thereby assign a function associated with the sample, there must be an alteration in the expression of that sample nucleic acid. Therefore, Applicant's assertion that the it does not matter that the transcription products are effective antisense or ribozyme molecule reads away from the very purpose of the claimed method, since the method requires an alteration in the sample nucleic acid in order to identify a function associated with it.

Moreover, Applicants are arguing the references of Wagner et al. and Gudkov et al. separately, and are not addressing the combination of these references as set forth in the prior Office Action. Although, according to Applicants the Gukdov et al. reference

reads on a method for identifying unknown sequences, and therefore is not related to Wagner et al. which is associated with targeting known genes, this point is irrelevant since the Gudkov et al. reference is relied upon since it provides specific guidance for amplifying and expressing the oligonucleotide constructs of the instant invention in cells without the use of bacterial cloning steps. Gudkov et al. provide methods for designing a retroviral library of nucleic acid fragments to be delivered to eukaryotic cells to test or determine the ability of these nucleic acid fragments to function as genetic suppressor elements (GSE) (see col. 10-12). The methods of Gudkov et al. essentially comprise methods for identifying gene function since the ability of the putative nucleic acid molecules to function, as a GSE is unknown prior to testing.

Although Applicants argue that the methods of Wagner et al. do not teach a high-throughput method, this newly added limitation does not render the claimed method non-obvious since the essential method is rendered obvious by the prior art, and it would have been obvious to the ordinary artisan to alter the parameters of a method known in the art to enhance, increase, or optimize the output of the method.

As stated in the prior Office Action, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the teachings of Wagner et al. with the teachings of Gudkov et al. in the design of the instant invention. One of ordinary skill in the art would have been motivated to make this modification since Wagner et al. expressly states that their disclosed methods for determining gene function may encompass wherein the transfection method comprises the use of retroviral vectors, and the teachings of Gudkov et al. are specifically designed to deliver

nucleic acid to cells using retroviral vectors with the express purpose of determining their ability to alter a phenotype of the transfected cells.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

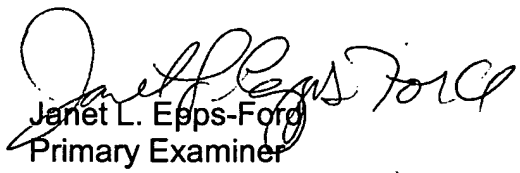
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Janet L. Epps-Ford
Primary Examiner
Art Unit 1633

*JLE*